K010964

JUL - 5 2001

OSTEOMED CORPORATION

510(k) Summary

Device Proprietary Name:	OsteoMed Auto-Drive Lag Screw System
Device Common Name:	Small Bone Screw
Classification Name:	Screw, Fixation, Bone
Name of Submitter:	OsteoMed Corporation 3750 Realty Road Addison, Texas 75001 Phone: (972) 241-3401 Fax: (972) 241-3507
Contact Person:	Dawn T. Holdeman
Date Prepared:	March 26, 2001

Summary:

This submission describes the OsteoMed Auto-Drive Lag Screw System indicated for osteotomies, fractures, or reconstructions of the craniofacial, maxillofacial, and mandibular bones as well as the bones of the hand and foot. Auto-Drive Lag Screws are intended for single patient use only.

The OsteoMed Auto-Drive Lag Screw System is comprised of screws ranging in diameters of 1.6mm to 2.4mm and in lengths ranging from 8mm to 42mm. Depth gauges, screwdrivers, countersinks, pilot drills, and preparation instruments will also be a part of the system.

Equivalence for this device is based on similarities in intended use, material, design and operational principle to the OsteoMed Auto-Drive Bone Screw (K974785), the M3 Lag Screw Fixation System (K924018), and the OsteoMed Super Screw Fixation System (K954330).

Due to the similarity of materials and design to both pre-enactment and post-enactment devices, OsteoMed believes that the OsteoMed Auto-Drive Lag Screw System does not raise any new safety or effectiveness issues.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL - 5 2001

Ms. Dawn T. Holdeman
Regulatory Affairs and Document Control
OsteoMed Corporation
3750 Realty Road
Addison, Texas 75001-4311

Re: K010964
Trade/Device Name: Auto-Drive Lag Screw System
Regulation Number: 888.3040
Regulatory Class: II
Product Code: HWC
Dated: June 28, 2001
Received: June 29, 2001

Dear Ms. Holdeman:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

OsteoMed "Indications for Use" Submission

510(k) Number: K010964

Device Name:	OsteoMed Auto-Drive Lag Screw
Indication for Use:	Indicated for osteotomies, fractures or reconstructions of the craniofacial, maxillofacial, and mandibular bones as well as the bones of the hand and foot. Auto-Drive Lag Screws are intended for single patient use only. The Auto-Drive Lag Screw System is not intended for use in and is contraindicated for: in cases of active or suspected infection or in patients who are immunocompromised; in patients previously sensitized to titanium; or in patients with certain metabolic diseases; in patients exhibiting disorders which would cause the patient to ignore the limitations of rigid fixation.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X
(Per 21 CFR 810.109)

Over-The Counter-Use _____
(Optical Format 1-)

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K010964